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Serial No.: 10/722,830  
Art Unit: 1732REMARKSDisposition of Claims

Upon entry of the foregoing amendments, claims 1, 3-4, 6-16, and 25-26 will be pending in the application and stand ready for further action on the merits. Claims 1 and 13 have been amended to clarify that the method of this invention is directed to shaping flexible dental nightguards or splints.

In one version of the method, a polymerizable composition is molded and shaped into a nightguard/splint structure within a patient's mouth. Then, the composition is irradiated with light so that it partially cures and hardens. After removing the partially cured nightguard/splint from the mouth, it is fully cured using a standard light-curing unit or other suitable device. The cured nightguard/splint is flexible, yet durable, having a flexural modulus of less than 250,000 psi and flexural strength of less than 7,000 psi at 37°C. In a second embodiment, the polymerizable composition is shaped over a plaster cast model of a patient's teeth. The composition is irradiated with light so that it cures and hardens. Then, the cured nightguard/splint can be removed from the cast model and placed in the patient's mouth.

The amendments made herein are supported throughout the specification, particularly at Example 8 (pages 10 and 11) and Example 11 (page 12) and by the originally filed claims. No new matter has been added to the application. Claims 2 and 5 have been canceled and their limitations have been incorporated into amended claim 1. In addition, dependent claims 6-12 have been amended to recite a "polymeric product" making these claims consistent with amended claim 1. Claims 17-24 have been canceled without prejudice or disclaimer of the subject matter contained therein. Lastly, new claims 25 and 26 have been added. These claims are supported by the specification, particularly at page 5, paragraph 2. Consistent with claims 6 and 7, new claims 25 and 26 recite the flexural modulus and strength of the product at 37 °C and 23 °C.

Claim Rejections under 35 U.S.C. §102

The Office Action makes several rejections of claims 1-24 under 35 U.S.C. §102(b) asserting that the claims are anticipated by Bowen, US Patent 5,792,821 ("Bowen '821") or Rusin et al., US Patent 6,437,010 ("Rusin"), or Bowen, US Patent 5,910,551 ("Bowen '551") or Völkel et al., US Patent 6,057,383 ("Völkel"), or Reiners et al., US Patent 4,843,136 ("Reiners") or Tateosian et al., US Patent 5,554,665 ("Tateosian").

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It is submitted that the presently claimed invention, as recited in amended claims 1, 3-4, 6-16, and new claims 25 and 26, is not anticipated over the disclosures in the foregoing references for the reasons discussed below.

Bowen '821 is directed to using cyclodextrin derivatives in dental adhesives and other materials. Formulations containing mixtures of polymerizable cyclodextrin derivatives (PCDs) can be used. As the Examiner points out, certain amine compounds (for example, 4-tert-butyl-N,N-dimethylaniline, abbreviated as TBDMA) can be used with photoinitiators such as camphorquinone in the polymerization of the PCD formulations. However, there is no disclosure or suggestion in Bowen '821 for shaping a flexible dental nightguard or splint as recited in the presently amended claims.

Rusin relates to glass ionomer cement systems which can be used in making dental restorations. The glass ionomer cement systems contain an organic composition that is substantially free of added water, a hydrophilic component, and an acid functional polymer; and an aqueous composition comprising water and an acid reactive filler. The ionomer cement systems can include photopolymerization initiators and accelerators such as amine compounds, for example, (for example, 4-tert-butyl-N,N-dimethylaniline, abbreviated as TBDMA) as noted by the Examiner. Upon exposure to ultraviolet or light visible sources, the cement cures and hardens. The resulting cement is durable and has low shrinkage. It can be used as dental restoratives, liners, bases, cements, sealants, and as dental or orthodontic adhesives (col. 12, lines 36-39). Rusin does not suggest using the glass ionomer cement systems to make flexible dental nightguards or splints.

Bowen '551 was granted on a divisional application that resulted in the above-described Bowen '821 Patent. The Bowen '551 and Bowen '821 references disclose compositions of polymerizable cyclodextrin derivatives (PCDs). Neither Bowen '551 nor Bowen '821 describes shaping flexible dental nightguards or splints from such compositions.

Völkel discloses making dental materials based on polymerizable waxes. In Völkel, multiple starting ingredients are mixed together to make the dental material. The ingredients include 0 to 70 wt. % of at least one polymerizable monomer and/or oligomer; 0.1 to 5 wt. % of at least one polymerization initiator; 0 to 60 wt. % of one or more fillers; and at least 20 wt. % of a wax-like polymerizable substance. Völkel discloses that the dental materials can be photopolymerized to make temporary and permanent prostheses as well as temporary crowns, bridges, and inlays. However, Völkel does not disclose or suggest using the polymerizable wax material to make a flexible dental nightguard or splint.

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The reference, Reiners discloses new methacrylate compounds of siloxanes containing tricyclodeneane groups. The compounds can be used as monomers and combined with conventional monomers such as methyl methacrylate. The composition can be subsequently polymerized to form dental filling materials and other products. Plastic teeth can be made using these compositions. However, Reiners does not suggest using these compounds to make flexible dental nightguards or splints.

Tateosian discloses using a method of making a denture reliner by mixing a first polymerizable paste composition with a second polymerizable paste composition. The first paste includes a polymerizable methacrylate, a peroxide, and a stabilizer such as butylated hydroxytoluene. The second paste includes a polymerizable methacrylate and a reducing agent for the peroxide such as dihydroxyethyl-p-toluidine. As the peroxide-containing paste and amine-containing paste are mixed with each other, they react and initiate polymerization and hardening of the composition. The composition relines the denture base. Tateosian fails to provide any teaching for a method which involves light-curing a polymerizable composition to make a flexible dental nightguard or splint as recited in the presently amended claims.

As the Examiner recognizes, a claim is anticipated under 35 U.S.C. §102(b) only if each and every element of the claim is found in a single prior art reference. Furthermore, a reference must enable one skilled in the art to make and use the claimed invention in order to be anticipatory. It is respectfully submitted there is no disclosure or suggestion for a method of making a flexible nightguard or splint as recited in the presently amended claims. Accordingly, it is respectfully requested that the rejections of claims 1-24 under 35 U.S.C. §102(b) be withdrawn.

#### Claim Rejections under 35 U.S.C. §103

The Office Action rejects claim 5 under 35 U.S.C. §103(a) as being unpatentable over Tregillis, US Patent 5,338,190 ("Tregillis") in view of Bowen, US Patent 5,792,821 ("Bowen '821") or Rusin et al., US Patent 6,437,019 ("Rusin"), or Bowen, US Patent 5,910,551 ("Bowen '551") or Völkel et al., US Patent 6,057,383 ("Völkel"), or Reiners et al., US Patent 4,843,136 ("Reiners") or Tateosian et al., US Patent 5,554,665 ("Tateosian").

Applicants agree with the Examiner that Tregillis discloses making dental appliances including nightguards. However, the method described by Tregillis is completely different than the method

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presently claimed by Applicants. Tregillis describes making the appliance using "lost wax" techniques (col. 1, lines 36-38).

A dental flask having bottom and upper half-portions, which can be pressed together, is used in a "lost wax" process. First, a temporary wax set-up resin is placed in the flask. Artificial teeth can be pressed into the wax resin while the resin is in a softened condition. The dental flask is filled with investing medium such as dental stone or gypsum. The flask portions are closed together and the flask is heated to melt the wax holding the artificial teeth. This step is referred to as "boiling out the wax" or "losing the wax" (col. 1, line 49). Then, the flask container is opened and each flask portion is placed face-up. One portion of the flask contains the set of artificial teeth embedded in dental stone. In the next step, a silicone shim is placed over the occlusal portion of the embedded teeth (col. 2, lines 50-53). Then, the polymerizable ethyl acrylate material is "packed into" the interior cavity of the flask. The acrylic composition is heat-cured so that it bonds to the buccal and lingual surfaces of the embedded teeth. The flask is opened and the silicone shim is removed. Then, a polymerizable methyl methacrylate material is "packed into" the interior cavity of the flask. The methyl methacrylate composition is heat-cured so that it bonds to the occlusal surfaces of the embedded teeth. In this manner, the heat-cured methyl methacrylate and ethyl acrylate materials are chemically bonded to each other. The resulting dental appliance is then removed from the flask.

As defined in amended claim 1 and as opposed to the method in Tregillis, the method of this invention involves shaping a polymerizable composition over the teeth. The material has good handling properties and can be molded and shaped easily so that it fits over the teeth. As discussed at page 5 of the Specification, the material is dimensionally stable and moldable under finger pressure at 23°C to 37°C. The shaped material is partially cured within the mouth using a standard dental curing light. Then, the material is fully cured to form a cured, flexible product. Likewise, as defined in amended claim 13, the polymerizable composition is placed over a model or cast of the patient's teeth. The composition is then cured by irradiating it with light. There is clearly no disclosure or suggestion for such methods in Tregillis. Thus, even if the disclosures in Tregillis and Bowen '821, or Rusin, or Bowen '551, or Völkel, or Reiners, or Tateosian were combined, the presently claimed invention would not be obvious to a person of ordinary skill in the art.

The methods of the present invention provide a flexible nightguard that a patient can easily handle and use to protect his/her teeth. The nightguard is resilient – it can be seated and removed easily by a patient. The nightguard has good retention – a patient can comfortably wear the nightguard while